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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,249	04/14/2004	Mark B. Knudson	13033.4USC5	8090

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EXAMINER	
GILBERT, SAMUEL G	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,249	KNUDSON ET AL.	
	Examiner	Art Unit	
	Samuel G. Gilbert	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 14 April 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2 papers. 7/12/2004 + 2/3/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

dss 6/25/05

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 7/12/2004 and 2/3/2005 have been considered. The lined through references have not been considered because proper dates have not been provided.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6-10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Magovern(5,979,456).

Claims 1, 2, 9, 10, and 12 - Magovern teaches a method of selecting and implanting a device into the pharyngeal wall to maintain the tissue in an open configuration. Applicant's attention is invited to figures 8-10 and column 7 line 51 through column 8 line 36. Further it is indicated that the structure can be formed by braided fibers, column 3 lines 36-43.

Claim 6 – it is the examiner's position that the material implanted would inherently induce at least some fibrotic response in said soft tissue.

Claims 7 and 8 - it is the examiner's position that keeping the airway open inherently treats sleep apnea and snoring.

Claims 1, 4-9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreiber (DE 44 12 190.3).

Schreiber teaches injecting an implant to treat rhonchopathy. It is the examiner's position that the injection of the material inherently causes a fibrotic tissue response. It is the examiner's position that collagen is fibrous by definition. It is also the examiner's position that injection of the implant into the body would induce at least some fibrotic response in the tissue. While treating snoring apnea would inherently be treated. The examiner is taking the soft palate to be in the nasal area of a patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubris (6,106,541) in view of Campbell et al (5,752,934).

Claims 1 and 2 - Hubris teaches a method of selecting an implant –10- and implanting it in nasal tissue, however the implant –10- does not include biocompatible fibers. Implant –10- is formed with an internal skeleton –24- and an encasing sheath –26-. The encasing sheath must be formed by a biocompatible material and sets forth polytetrafluroethylene as an example. However fibers and braided material have not been set forth. Campbell et al teaches a catheter including a balloon including an encasing sheath formed by a braid of polytetrafluroethylene over the balloon for the purpose of providing chemical inertness and low coefficient of friction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a braided encasing as taught by Campbell as a substitution of functionally equivalent encasing elements since both are a biocompatible material encasings.

Claim 6 – it is the examiner's position that the material implanted would inherently induce at least some fibrotic response in said soft tissue.

Claims 7 and 8 - it is the examiner's position that keeping the nasal passages open inherently treat sleep apnea and snoring.

Claim 11 – the implant is in the nasal area.

Claim 12 – the implant is permanent.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magovern(5,979,456) as applied to claim 1 above, and further in view of Durgin et

al(6,221,039). Magovern teaches a method as claimed but does not teach a twisted construction. Durgin et al. teach that nitinol wires can be single strand, multi strand, braided or twisted wire therefore the structures are functional equivalents in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a twisted wire construction in place of the braided construction of Magovern because the selection of functionally equivalent structures would have been an ordinary design expedient to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,848,447. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,516,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,523,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,634,362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,742,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No.

6,513,530. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,453,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,450,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are obvious modifications in the scope of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Samuel G. Gilbert
Primary Examiner
Art Unit 3736

sgg